UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

LINDA F. HOOPER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 1:20-CV-191-CEA-HBG
	)	
ETHICON, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This case is before the undersigned pursuant to 28 U.S.C. § 636, the Rules of this Court, and Standing Order 13-02.

Now before the Court is Defendants' Motion to Limit the Case-Specific Testimony of Ralph Zipper, M.D. ("Defendants' Motion to Limit") [Doc. 115] and Plaintiff's Motion to Limit the Opinions and Testimony of Dr. Salil Khandwala, M.D. ("Plaintiff's Motion to Limit") [Doc. 117]. The parties appeared before the undersigned for a motion hearing on July 2, 2021. Attorneys Adam Davis and Diane Watkins appeared on behalf of Plaintiff. Attorneys Amy Pepke and Kari Sutherland appeared on behalf of Defendants. Accordingly, for the reasons discussed below, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motion to Limit [**Doc. 115**] and **DENIES AS MOOT** Plaintiff's Motion to Limit [**Doc. 117**].

I. BACKGROUND

On June 3, 2010, Plaintiff underwent an operation performed by Dr. Steele to implant the Prolift + M device ("Device") following a diagnosis of pelvic organ prolapse and symptomatic rectocele. The implant surgery was performed at Erlanger Health System in Chattanooga, Tennessee. Plaintiff alleges that in 2012, she began suffering from a variety of painful injuries,

including vaginal burning and swelling, more frequent urination (urgency), pelvic pain, vaginal pain, dyspareunia, and emotional suffering due to the continuing physical issues and inability to have sexual relations. Plaintiff alleges that the Device caused her to suffer the above problems.

Relevant to the instant matter, Plaintiff has designated Ralph Zipper, M.D., a urogynecologist, as a case-specific expert witness, and Defendants have designated Salil Khandwal M.D., a urogynecologist, to offer general and case specific opinions. Each party has challenged the opposing party's expert's opinions.

II. STANDARD OF REVIEW

"Federal Rule of Evidence 702 obligates judges to ensure that any scientific testimony or evidence admitted is relevant and reliable." *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 147 (1999) (quoting *Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579, 589 (1993)). Specifically, Rule 702 provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert,* the Supreme Court of the United States stated that a district court, when evaluating evidence proffered under Rule 702, must act as a gatekeeper, ensuring "that any and all

scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589. The *Daubert* standard "attempts to strike a balance between a liberal admissibility standard for relevant evidence on the one hand and the need to exclude misleading 'junk science' on the other." *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 176–77 (6th Cir. 2009).

The factors relevant in evaluating the reliability of the testimony, include: "whether a method is testable, whether it has been subjected to peer review, the rate of error associated with the methodology, and whether the method is generally accepted within the scientific community." *Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 970-71 (M.D. Tenn. 2002) (citing *Daubert*, 509 U.S. at 593–94). Rule 702 inquiry as "a flexible one," and the *Daubert* factors do not constitute a definitive checklist or test. *Kumho Tire Co.*, 526 U.S. at 138-39 (citing *Daubert*, 509 U.S. at 593); *see also Heller v. Shaw Indus., Inc.,* 167 F.3d 146, 152 (3d Cir. 1999) (explaining that these factors "are simply useful signposts, not dispositive hurdles that a party must overcome in order to have expert testimony admitted").

"Although *Daubert* centered around the admissibility of scientific expert opinions, the trial court's gatekeeping function applies to all expert testimony, including that based upon specialized or technical, as opposed to scientific, knowledge." *Rose v. Sevier Cty., Tenn.*, No. 3:08-CV-25, 2012 WL 6140991, at *4 (E.D. Tenn. Dec. 11, 2012) (citing *Kumho Tire Co.*, 526 U.S. at 138-39). "[A] party must show, by a 'preponderance of proof,' that the witness will testify in a manner that will ultimately assist the trier of fact in understanding and resolving the factual issues involved in the case." *Coffey*, 187 F. Supp. 2d at 70-71 (quoting *Daubert*, 509 U.S. at 593-94). The party offering the expert has the burden of proving admissibility. *Daubert,* 509 U.S. at 592 n. 10.

Moreover, the Supreme Court has explained that in determining "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact," the court must

assess "whether the reasoning or methodology underlying the testimony is scientifically valid and whether it can properly be applied to the facts in issue." *Id.* at 592–93. "Furthermore, the court must examine the expert's conclusions in order to determine whether they can reliably follow from the facts known to the expert and the methodology used." *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *7 (E.D. Pa. Feb. 1, 2001) (citing *Heller,* 167 F.3d at 153).

Further, a court should "exclude proffered expert testimony if the subject of the testimony lies outside the witness's area of expertise." *In re Diet Drugs*, 2001 WL 454586, at *7 (quoting 4 Weinstein's Fed. Evid. § 702.06[1], at 702–52 (2000)). This simply means that "a party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue." *Id.* (other citations omitted).

Finally, "the court will not exclude expert testimony merely because the factual bases for an expert's opinion are weak." *Andler v. Clear Channel Broad., Inc.*, 670 F.3d 717, 729 (6th Cir. 2012) (quotation marks and citations omitted). Exclusion is the exception, not the rule, and "the gatekeeping function established by *Daubert* was never 'intended to serve as a replacement for the adversary system.'" *Daniels v. Erie Ins. Group*, 291 F. Supp. 3d 835, 840 (M.D. Tenn. Dec. 4, 2017) (quoting *Rose v. Matrixx Initiatives, Inc.*, No. 07–2404–JPM/tmp, 2009 WL 902311, at *7 (W.D. Tenn. March 31, 2009)) (other quotations omitted). Rather, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert,* 509 U.S. at 596. Rule 702 does not "require anything approaching absolute certainty." *Daniels*, 291 F. Supp. 3d at 840 (quoting *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671–72 (6th Cir. 2010)).

III. ANALYSIS

The Court has considered the parties' positions and the oral arguments at the hearing. Accordingly, for the reasons discussed below, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motion to Limit [**Doc. 115**] and **DENIES AS MOOT** Plaintiff's Motion to Limit [**Doc. 117**].

The Court will first discuss Defendants' challenges to Dr. Zipper's opinions and then turn to Plaintiff's challenges Dr. Khandwala's opinions.

A. Dr. Zipper

Defendants move to exclude several of Dr. Zipper's opinions, arguing that he is not qualified to render such opinions and that his opinions are irrelevant, speculative, unreliable, and without foundation. Specifically, Defendants assert six main challenges to Dr. Zipper's opinions. First, Defendants state that Dr. Zipper is not qualified to opine on product warnings, including what information the instructions for use ("IFU") should contain. Second, Defendants state that Dr. Zipper's opinions regarding informed consent are irrelevant. Third, Defendants argue that Dr. Zipper's opinion on the technical pearls is irrelevant. Fourth, Defendants challenge Dr. Zipper's opinion that the Device was defective or that Plaintiff was injured by the defect, stating that such opinions are irrelevant, speculative, unreliable, and without foundation. Fifth, Defendants state that Dr. Zipper's opinions regarding prognosis and future care are speculative. Finally, Defendants argue that Dr. Zipper's alternative design opinions are irrelevant in this case.

The Court will address each challenge separately, unless otherwise noted.

1. Qualifications and Informed Consent

Defendants argue that Dr. Zipper is not qualified to opine that the IFU should have included additional warnings about the alleged risks related to implantation and that the lack of this

information prevented Plaintiff from making an informed decision. In support of their position, Defendants state that the MDL court held that while an urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should be included in the IFU. In addition, Defendants assert that that the learned-intermediary doctrine renders Dr. Zipper's informed consent opinions irrelevant.

During the hearing, Plaintiff stated that she does not intend to illicit testimony from Dr. Zipper regarding whether the warnings on the IFU were adequate. In response, Defendants stated that their Motion is now moot with respect Dr. Zipper's opinions regarding the adequacy of the IFU. Accordingly, based on the parties' representations, the Court finds this issue moot. Further, given that Dr. Zipper does not intend to testify about the adequacy of the IFU warnings, the Court also finds Defendants' arguments regarding Dr. Zipper's opinions about informed consent moot. Accordingly, the Court finds Defendants' Motion on this issue **DENIED AS MOOT.**

2. Technical Pearls

Defendants assert that Dr. Zipper's opinion regarding the technical pearls method is irrelevant. Defendants state that while Dr. Zipper opines that such teaching methods teach away from safety and toward morbidity including chronic buttock pain, leg pain, numbness and loss of motor function, Plaintiff does not claim to have suffered any of these injuries that Dr. Zipper associates with this technique. Thus, Defendants state that Dr. Zipper's opinion on the technical pearls is irrelevant.

Plaintiff states that Dr. Zipper's case specific report reveals that he identified other known injuries associated with Ethicon's insertion method, including myofascial pelvic pain, extrapelvic pain syndrome, pain with ambulation, dyspareunia, and so forth, some of which Plaintiff

experienced. Plaintiff also claims that Dr. Zipper's testimony is relevant to the failure to warn claim because he opines that Ethicon taught techniques known to cause nerve injury and pain and that Ethicon did not warn physicians that the method and implantation could not be reversed to facilitate explanation. Defendants reply that evidence of complications that Plaintiff did not experience is irrelevant and lacking in probative value.

Dr. Zipper's expert report includes a section titled, "Ethicon Taught Methods That Encouraged Pain, Dyspareunia, and Visceral Dysfunction." [Doc. 115-2 at 19]. Specifically, Dr. Zipper explains that instead of teaching hyperflexion of the hip, Ethicon taught, "The patient should be placed in the lithotomy position with her buttocks slightly overlapping the table and her thighs flexed at approximately 90 degrees in relation to the plane of the table." [*Id.* at 20]. Ethicon's insertion method requires a blind passage of a long trocar to the area of fixation, within millimeters of vital nerves, blood vessels, and organs. [*Id.* at 22]. Dr. Zipper concludes, "The teachings of the Technical Pearls are ambiguous and teach away from safety and toward morbidity including chronic buttock pain, leg pain, numbness and loss of motor function." [*Id*. at 21].

Dr. Zipper opines that the "noxious effects of polypropylene mesh on the muscles of the pelvic often cause extrapelvic pain syndromes." [*Id*. at 20.]. Dr. Zipper identifies problems that are associated with Ethicon's method, including myofascial pelvic pain, difficulty with ambulation, and dyspareunia. [*Id.* at 20, 23-24]. During Dr. Zipper's physical examination of Plaintiff, Plaintiff described severe pressure like pain during sexual intercourse and later intermittently pain throughout the day, especially when exercising. [Doc. 115-2 at 39]. Plaintiff's present symptoms include a constant pressure of heaviness in the suprapublic area and vulva and dyspareunia. [*Id.* at 37]. Dr. Zipper diagnosed Plaintiff with pelvic floor tension myalgia and associated myofascial pain and dyspareunia. [*Id.* at 38-40].

The Court finds Defendants' arguments regarding Dr. Zipper's testimony about the technical pearls method not well taken. Dr. Zipper identified other issues resulting from use of this method, some of which Plaintiff experienced. Although it does not appear that Plaintiff has alleged that she experienced buttock pain, leg pain, and numbness, or loss of motor function, Defendants may emphasis such facts during their cross examination of Dr. Zipper. Accordingly, the Court will not exclude Dr. Zipper's testimony regarding the technical pearls on this basis, and Defendants' Motion on this issue is **DENIED**.

3. Defective Device and Causation

Defendants assert that under Tennessee law, Dr. Zipper's opinions about Plaintiff's Device are not relevant unless Plaintiff can show that the Device was defective and that such defect was the proximate cause of her injuries. Defendants state that there is no reliable evidence that Plaintiff's mesh manifested any of the alleged characteristics cited by Dr. Zipper. In addition, Defendants argue that Dr. Zipper's report fails to identify the specific defect to which he attributes to Plaintiff's injuries.

Plaintiff argues that the Court should allow Dr. Zipper to testify about the defects in the Device and the connection between those defects and Plaintiff's injuries. Plaintiff explains that Dr. Zipper identified multiple defects in the Device, including the method of insertion and the material used to manufacture the Device (polypropylene mesh) and in the Device itself. Plaintiff explains that Dr. Zipper personally examined Plaintiff, reviewed her medical history, and performed a differential diagnosis. Plaintiff argues that Defendants' challenges go to the weight of Dr. Zipper's opinions and not to their admissibility.

Defendants reply that Plaintiff's arguments miss the point. Defendants state that there is no evidence that Plaintiff's mesh curled, roped, frayed, or degraded, and that Plaintiff's position

that all polypropylene mesh degrades is insufficient. Defendants contend that Dr. Zipper's bare assertions that the mesh had abnormalities and had undergone certain changes do not provide any information as to whether an alleged defect in the Device was specifically causing Plaintiff's symptoms.

In Dr. Zipper's expert report, he explains the issues with the Device's material, design, and implantation, which have contributed to Plaintiff's symptoms. With respect to the material, Dr. Zipper explains that the mesh implants are made with polypropylene mesh (PPM). [Doc. 115-2 at 7]. The human body attacks the PPM because it is a foreign body. [*Id.*]. The body releases chemicals, such as oxygen, hydrogen peroxide, and hypochlorite, which eventually causes the PPM to become brittle and degrade. [*Id.* at 8]. In addition, in response to the foreign body (*i.e.*, the PPM), the body also releases chemical messengers known as cytokines. [*Id*. at 10]. These cytokines are responsible for recurring more inflammatory cells. [*Id*.]. As the PPM continues to degrade, it creates a rougher surface area and more acute and chronic inflammation. [*Id*.]. In other words, given the continuing release of chemicals as part of the foreign body reactions, the PPM continues to degrade. [*Id*.].

With respect to the design, Dr. Zipper opines that the Device has multi-armed, muscle piercing transvaginal mesh kits that are associated with severe and concerning contraction. Dr. Zipper relies on studies that found that mesh implants significantly shrink within six weeks of implantation and that contraction can led to recurrent pelvic organ prolapse. [*Id.* at 11]. Specifically, Dr. Zipper relied on a study that noted, "We hypothesize that, when severe mesh retraction occurs, a significant part of the bladder or rectum (usually the distal part) becomes uncovered by the mesh, allowing prolapse recurrence to occur at this unprotected part of the vaginal wall, particularly in cases of weak native tissue" and that "it is known that mesh retraction

is related [to] tissue inflammation around the mesh after implantation." [*Id.*] (internal quotations omitted).

Dr. Zipper outlined Plaintiff's medical history in his report. [*Id.* at 28-35]. On June 14, 2017, Dr. Zipper physically examined Plaintiff. [*Id*. at 35]. Plaintiff discussed with Dr. Zipper her medical history and the issues and symptoms that she had before the implantation of the Device and afterwards. [*Id.* at 35-38]. Dr. Zipper further described as follows:

> My [e]xamination of Ms. Hooper demonstrated mesh fiber exposed through the posterior vaginal mucosa, at the midline, at approximately minus 5 centimeters. The surrounding mucosa was erythematous and friable. I found bilateral bounds, consistent with contracted mesh arms, coursing into the right and left sacrospinous ligaments and coccygeus muscle. Mild to moderate pressure on these bands elicited severe pain ("10/10" pain) that duplicated her pain with intercourse and was "like the pain I get in gym. It feels like bricks are down here" (She put her hands in the suprapubic area). These bands were palpated rectally with identical findings. I found moderate hypertonus and tenderness of the levator ani muscle group. I identified stage two anterior and posterior compartment failure. There was mild loss of rugation of the vaginal mucosa.

[*Id.* at 38].

Dr. Zipper concludes that Plaintiff's pain and pressure is more likely than not the result of the Device related pelvic floor tension myalgia. [*Id*.]. Dr. Zipper states that when Dr. Steele treated Plaintiff for ongoing mesh erosion and pain by removing a piece of the eroded mesh, there was no connective tissue left to prevent a recurrent rectocele. [*Id*. at 39]. Dr. Zipper further opines that the defective Device and method of insertion caused pelvic floor tension myalgia and myofascial pain, dyspareunia, and that she has signs of atrophy but no symptoms. [*Id.* at 40-41]. Dr. Zipper performed a differential diagnosis in support of his opinion. [*Id*. at 41]. Dr. Zipper concludes as follows:

> My opinion, to a reasonable degree of medical certainty is that the defects of the PROLIFT +M material, including but not limited to the material mismatch associated with polypropylene mesh, the inadequate pore size, the resultant chronic foreign body reaction, chronic inflammation, deformation, loss of pore size, fibrotic bridging with scar plate formation, shrinkage, contraction, and inability to completely remove the device were the cases of [Plaintiff's] present mesh erosion, her multiple symptomatic mesh extrusions, the multiple mesh excision procedures and the chemical cauterization suffered by [Plaintiff].

[*Id.* at 45].

As mentioned above, Defendants assert that Dr. Zipper cannot testify that the Device was defective or that Plaintiff was injured by Device's defects. Defendants state that Plaintiff's mesh has not been pathologically tested and that such defects cannot be seen with the naked eye. In a similar vein, Defendants assert that Dr. Zipper cannot testify that the alleged defects caused Plaintiff's injury because he does not adequately explain how he concluded that the alleged deformations or other characteristics in Plaintiff's mesh resulted in her purported injuries. Defendants argue that Dr. Zipper fails to identify the defect, out of the laundry list of purported defects, that applies to Plaintiff's mesh, and he fails to attribute the specific alleged injury to the specific defect.

The Court finds that Defendants' arguments go the weight of Dr. Zipper's opinions and not to their admissibility. *Andler v. Clear Channel Broad., Inc.*, 670 F.3d 717, 729 (6th Cir. 2012) ("The court will not exclude expert testimony merely because the factual bases for an expert's opinion are weak."). The Court notes a similar issue was raised in *McBroom v. Ethicon, Inc.,* wherein defendants argued that plaintiff's expert witness should be excluded because he did not connect any of plaintiff's injuries to a defect in the TVT and Prolift. No. CV-20-02127-PHX-DGC, 2021 WL 1208976, at *5 (D. Ariz. Mar. 31, 2021). In other words, defendants contended that the mere assertion that the presence of the devices caused injury is not sufficient to render the

expert witness's causation opinions relevant and reliable because plaintiff ultimately must prove that a defect in the devices were the proximate causes of her injuries. *Id*. The court disagreed with defendants' arguments, explaining that the expert witness employed a differential diagnosis in reaching his causation opinions. *Id*. In addition, the court noted that the expert did list the defects that caused plaintiff's injuries and explained that defendants' complaint that the list of alleged flaws is the standard-wrap up paragraph for the specific expert witness was not a basis for exclusion. *Id.* at *6, n. 7.

Similarly, as outlined above, Dr. Zipper performed a differential diagnosis to explain why the defects contributed to Plaintiff's issues and why he was able to rule out other potential causes. In support of their position, Defendants rely on *Huskey v. Ethicon*, Inc., 29 F. Supp. 3d 691 (S.D. W.Va. 2014), wherein the court held that the opinions of the expert witness (Dr. Rosenzweig) on degradation, fraying and particle loss were not sufficiently reliable. *Id.* at 708. The Court finds *Huskey* distinguishable because in *Huskey*, the court explicitly noted that Dr. Rosenzweig did not attempt to rule out potential causes for the Plaintiff's symptoms. *Id.*; *see also Dorgan v. Ethicon, Inc*., No. 4:20-00529-CV-RK, 2020 WL 5367062, at *3 (W.D. Mo. Sept. 8, 2020) (finding *Huskey* distinguishable because Dr. Rosenzweig had performed a differential diagnosis after reviewing the medical records); *see also Meindertsma v. Ethicon Inc*., No. 1:20-CV-00708-RP, 2021 WL 2010355, at *7 (W.D. Tex. May 17, 2021) (holding that although the expert did not personally examine the mesh or the plaintiff, his differential diagnosis was reliable and that Ethicon's challenges were to the weight of the opinion).

The Court finds Defendants can address their concerns with Dr. Zipper's opinions through vigorous cross examination and the presentation of contrary evidence, but Defendants' arguments

are not grounds for exclusion. Accordingly, the Court finds that Defendants' arguments are not well taken, and the Motion on this issue is **DENIED**.

4. Prognosis and Future Care

Defendants state that Dr. Zipper offers several opinions regarding Plaintiff's prognosis and future care. Defendants assert that these opinions are pure speculation, stating that Dr. Zipper frequently resorts to hypothetical and conditional phrasing. Defendants contend that the MDL court has previously scrutinized and excluded similar opinions as to future treatment and complications that have no basis in fact.

Plaintiff asserts that Defendants' reliance on the MDL court's opinion is misleading. Plaintiff argues that Dr. Zipper lists the bases for his opinion and the level of certainty and the likelihood of a particular event happening in the future, as well as the possible treatment modalities that would be needed. Plaintiff asserts that Defendants can attack Dr. Zipper's opinions during cross examination.

In the present matter, Dr. Zipper offers several opinions regarding Plaintiff's prognosis and future care. [Ex. 115-2 at 45-67]. Specifically, Dr. Zipper concludes as follows: (1) Plaintiff's present mesh extrusion is unlikely to resolve without surgical intervention, (2) that her untreated compartment failure will worsen without treatment, (3) she remains at an increased risk for further re-surgery for the duration of her lifetime, (4) complete removal of the Device from Plaintiff may be impossible and that attempts to remove it may worsen her condition, (5) her pelvic pain and dyspareunia will more likely than not continue in perpetuity, and (6) she will continue to suffer from permanent, chronic pelvic pain and vaginal pain, and that without colpocleisis, Plaintiff will remain with a recurrent rectocele for the remainder of her life. [*Id.*].

The Court finds Dr. Zipper's opinions regarding prognosis and future care admissible. In rendering his opinions, Dr. Zipper relies on Plaintiff's medical history, his examination of Plaintiff, the medical literature, and his experience. *Warren v. C. R. Bard, Inc.*, No. 8:19-CV-2657-T-60JSS, 2020 WL 1899838, at *3 (M.D. Fla. Apr. 17, 2020) (finding Dr. Zipper's opinions concerning possible future adverse events supported by the record, sufficiently grounded, and admissible). In support of their argument, Defendants rely on *Edwards v. Edwards*, No. 2:12-CV-09972, 2014 WL 3361923, (S.D. W. Va. July 8, 2014), stating that the court excluded another expert from rendering similar testimony. In *Edwards*, however, the court noted that the expert "is a pathologist, not a treating physician, and he has never examined [plaintiff.]." *Id*. at *26. The Court finds *Edwards* distinguishable because Dr. Zipper regularly treats patients for mesh-related complications, he performed an examination of Plaintiff, and he performed a differential diagnosis in this case. Accordingly, the Court finds that Defendants' arguments are not well taken, and the Motion on this issue is **DENIED**.

5. Alternative Design Opinions

Defendants assert that Dr. Zipper offers an ambiguous safer alternative design opinion. Defendants state that Dr. Zipper does not identify any specific safer alternative designs but instead mentions native tissue repair, allograft, and xenograft repairs. Defendants assert that proof of an alternative design is not required in Plaintiff's prima facie case, but it is a key component of Tennessee's risk-utility analysis. Defendants contend that Dr. Zipper's purported alternatives are not actual designs but instead non-mesh alternative treatments. Defendants state that another remand court recently precluded Dr. Zipper from offering a similar opinion.

Plaintiff states that Dr. Zipper opines that there are safer and feasible alternative designs, treatments, and methods that were available at the time of Plaintiff's implant procedure. Plaintiff

asserts that evidence of non-mesh alternatives is relevant to assessing the utility of Ethicon's products to other aspects of Plaintiff's claims and to counter Ethicon's assertions that its products are the gold standard for treating stress urinary incontinence and pelvic organ prolapse. In addition, Plaintiff argues that Dr. Zipper's opinions are relevant to her failure to warn and negligence claims.

Plaintiff states that even if this Court concludes that an alternative must be a product to be relevant, Dr. Zipper offers several alternative products to the Device. For instance, Plaintiff states that Dr. Zipper opines that the Device could have been designed using a mesh with larger pores and/or a lighter mesh, and he specifically lists the Smartmesh and Restorelle as safer alternative products. Plaintiff also submits that in Dr. Zipper's general report, he states that "the use of self-tailored directly fixated mesh would remove the large group of trocar and arm related complications." [Doc. 121 at 18]. Plaintiff continues that if the Court does not permit Dr. Zipper to testify about procedures, the Court should allow his testimony about allografts and autologous fascia slings, as well as mesh with larger pores or different features such as rounder, thinner arms. Plaintiff explains that Defendants' argument that the use of allografts creates an entirely different type of product creates a factual issue that should go to the jury.

Defendants reply that Smartmesh and Restorelle are not included in Dr. Zipper's case-specific opinions. Defendants deny that a native tissue repair is an alternative design and state that allografts contain tissue from another human, which are not comparable to synthetic mesh devices.

In the present matter, Dr. Zipper opines as follows:

> Based on my experience including the thousands of women I have treated for pelvic organ prolapse, as well as my knowledge, training, review of medical literature and other materials, it is my opinion that safer and feasible alternative designs and treatments are available

> and were and to [Plaintiff] at the time of her PROLIFT +M implantation procedure.
>
> By way of example, a native tissue repair of her rectocele would have provide[d] at least an equal symptomatic improvement and would have been associated with either a lower risk or no risk of each of the PROLIFT + M related complications suffered by [Plaintiff].
>
> In addition to native tissue repair of the posterior compartment, site specific allograft and xenograft surgery could have been used to treat [Plaintiff's] rectocele. These biograft repairs provide similar subjective improvements and are not associated with persistent and recurrent erosions, chronic vaginal dysbiosis, and the high rate of dyspareunia known to PROLIFT.

[Doc. 115 at 72-73]. In his general causation report, Dr. Zipper further opines that the historical sacrolopopexy has been shown to be a safer, more effective method of treating apical POP that results in higher patient satisfaction. [Doc. 121-7 at 185]. He also opines in his general causation report that other meshes (Smartmesh and Restorelle) are safer than the Gynemesh PS (Prolift). [*Id*.]. Dr. Zipper further states that Ethicon could have used a lighter mesh, a mesh with larger pores, and a mesh without arms or different shapes. [Doc. 115-2 at 13-15, Doc. 121-7 at 109].

As mentioned above, Defendants object to the above testimony, arguing that it is irrelevant because Dr. Zipper offers different procedures and not designs, and Plaintiff responds that such testimony is relevant for other reasons. As an initial matter, the Court notes that the parties agree that under the Tennessee Products Liability Act, Plaintiff is not required to prove the existence of an alternative design. Plaintiff insists that Dr. Zipper's opinion is relevant to the utility of the design.

The Tennessee Products Liability Act states, in part, as follows, "A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it

left the control of the manufacturer or seller." Tenn. Code Ann. § 29-28-105(a). In determining if a product is defective or unreasonably dangerous, "Consideration is given also to the customary designs, methods, standards, and techniques of manufacturing, inspecting, testing by other manufacturers or sellers of similar products." Tenn. Code Ann. § 29-28-105(b).

The Court finds evidence of other procedures, as opposed to designs, irrelevant and confusing to the jury. *Hosbrook v. Ethicon, Inc.*, No. 3:20-CV-88, 2021 WL 1599199, at *4 (S.D. Ohio Apr. 23, 2021) ("To introduce evidence of alternative surgical procedures in a product liability case is irrelevant and would create confusion for the jury."). The Court agrees with Defendants that offering alternative procedures takes issue with Plaintiff's physician's treatment choices as opposed to the alleged issues with the Device. *See Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 907 (S.D. Iowa 2020) ("The choice of a surgery over a device is a matter of medical judgment of treating doctors, not whether there is a safer alternative design for the product.").

In support of her position, Plaintiff argues that alternative procedures and designs are relevant to the risk-utility test utilized in Tennessee. The Tennessee Products Liability Act provides for two tests to determine whether a product is unreasonably dangerous: the consumer expectation test and the prudent manufacturer test. *Brown v. Crown Equip. Corp.*, 181 S.W.3d 268, 282 (Tenn. 2005). The Court does not find evidence of alternative procedures relevant to either test or to Plaintiff's failure to warn or negligence claim. The Court finds such evidence misleading and confusing in a products liability case.[1]

[1] Defendants acknowledged at the hearing that their witnesses will not testify that their product is the "gold standard," and that if they did testify to such, the testimony would open to the door to the evidence that they requested be excluded.

Plaintiff also asserts that Dr. Zipper has provided products, citing to allografts. Plaintiff states that an allograft is a sling. [Doc. 121 at 19]. During the motion hearing, Defendants explained that a native tissue repair is a procedure because a physician simply attaches the tissue with sutures. In addition, Defendants explained that the slings can either be made with the patient's own tissue (autologous slings) or with tissue from a cadaver (allograft slings). Defendants stated that these slings are not similar to the syntenic mesh at issue and that the slings are regulated differently. The Court will not preclude Dr. Zipper from testifying about the slings.[2] The Court finds that the slings are relevant to the risk-utility analysis and that the differences between the Device at issue and the slings are facts that the jury should consider. In addition, Defendants state that while Plaintiff argued that the allograft is a safer product to treat stress urinary incontinence, Plaintiff was implanted with the Device to treat pelvic organ prolapse. This, issue, however, can be raised during cross examination.

Finally, Plaintiff states that Dr. Zipper also opined that Smartmesh and Restorelle are safer alternative products. Defendants respond that these opinions were not in Dr. Zipper's case specific report. The Court agrees with Defendants that Dr. Zipper cannot suggest these products as safer alternative designs for Plaintiff as he did not suggest them in his case-specific report. Accordingly, the Court finds Defendants' argument well taken, in part. The Courts finds Dr. Zipper may only

[2] During the hearing, the parties did not specifically discuss xenografts, but it appears to the Court that xenografts are similar to allografts, except that xenografts are made with tissue from animal donors. *See Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 900 (S.D. Iowa 2020) ("Allografts and xenografts are made of natural donor tissue—human cadaver donors, in the case of allografts, and animal donors, in the case of xenografts.").

testify to allografts, xenografts, and a lighter mesh with larger pores. Accordingly, Defendants' Motion on this issue is **GRANTED IN PART AND DENIED IN PART.**

B. Dr. Khandwala

Plaintiff moves to limit Dr. Khandwala opinions, arguing that his opinions exceed the bounds of his qualification and that they are founded on insufficient facts and unreliable methodology. Specifically, Plaintiff objects to Dr. Khandwala's opinions that the IFU is adequate or any opinions regarding what warnings the IFU should or should not include.

During the hearing, Plaintiff stated that her Motion may be moot if Defendants agreed that Dr. Khandwala's opinions regarding the IFU and patient brochures would be limited to stating what he believes are risks or not risks associated with the Device and stating what is or is not in the IFU and patient brochures. Plaintiff states that Dr. Khandwala cannot testify that the IFU and patient brochures were adequate. Defendants agreed to Plaintiff's proposal regarding Dr. Khandwala's testimony. Accordingly, given the parties' agreement, the Court **DENIES AS MOOT** Plaintiff's Motion [**Doc. 117**].

IV. CONCLUSION

Accordingly, for the reasons explained above, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motion to Limit the Case-Specific Testimony of Ralph Zipper, M.D. [**Doc. 115**] and **DENIES AS MOOT** Plaintiff's Motion to Limit the Opinions and Testimony of Dr. Salil Khandwala, M.D. [**Doc. 117**].

IT IS SO ORDERED.

ENTER:

Bruce Guyton

United States Magistrate Judge